United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7508P)

EPA 738-R-07-001

Reregistration Eligibility Decision for Allethrins

Reregistration Eligibility Decision (RED) for Allethrins

List C

Case No. 0437

Approved by: _____

Pete Caulkins, Ph.D., Acting Director
Special Review and Reregistration Division

Date: June 29, 2007

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Glossary of Terms and Abbreviations

ai	Active Ingredient
CFR	Code of Federal Regulations
CSF	Confidential Statement of Formula
DCI	Data Call-In
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
G	Granular Formulation
GLN	Guideline Number
HP	High pressure
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
LP	Low pressure
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
N/A	Not Applicable
NDETF	Non-Dietary Exposure Task Force
NLAA	Not Likely to Adversely Affect
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PCA	Percent Crop Area
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts per Million
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TGAI	Technical Grade Active Ingredient
USDA	United States Department of Agriculture
UF	Uncertainty Factor
UF_{db}	Database Uncertainty Factor

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Abstract

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for the allethrins and is issuing its risk management decision. The allethrin series of pyrethroid insecticides includes bioallethrin (PC code 004003), esbiol (004004), esbiothrin (004007, formerly 004003/004004), and pynamin forte (004005). The allethrins are not registered for use on food, and they have no U.S. tolerances associated with their use; therefore, they are not subject to Food Quality Protection Act (FQPA). The risk assessments, which are summarized below, are based on the review of the required database supporting the use patterns of currently registered products and additional data provided by the technical registrants, Valent BioSciences Corporation and Sumitomo Chemical Company, Ltd.

The allethrins are used to control flying and crawling insects in a number of commercial, horticultural and residential applications. Commercial applications include space, broadcast and crack and crevice treatment in a variety of commercial, industrial, residential, and institutional sites. Horticultural applications include foliar and fogger treatment on non-food plants. Residential uses include pest control in homes and outdoor domestic structures, on gardens and direct application to cats, dogs and horses. The registered uses of the allethrins are not expected to adversely impact groundwater or surface water; therefore, a drinking water assessment was not performed. Because there are no food uses or potential exposures to drinking water, the reregistration action considered potential residential, occupational, and ecological risk.

For residential handler risk, all scenarios assessed were greater than the Agency's Level of Concern (LOC), i.e., the Margins of Exposure (MOEs) were above 1000. For residential post-application risk, the MOEs are all greater than the target MOE of 1000 after mitigation measures are incorporated, except for inhalation exposures from yard and patio total release foggers. However, the Agency does not anticipate a risk of concern from this use.

Occupational handler and post-application inhalation exposures were assessed. Most of the inhalation MOEs are greater than the Agency's target occupational MOE of 100 without respirators, and therefore, the inhalation risks are not of concern. The high pressure handwand scenario is of concern without respirators and requires a dust mask to achieve the target MOE. The space spray fogger scenario is also of concern and requires a PF50 full face respirator with appropriate cartridges to achieve the target MOE, as well as a maximum concentration reduction from 3.0% ai to 1.5% ai in product. The MOEs for the occupational post-application scenarios assessed exceed the Agency's target MOE of 00 and are not of concern.

The Agency evaluated potential ecological risk from both indoor and outdoor uses of the allethrins. The technical registrant voluntarily agreed to cancel pet shampoos and dips; therefore, there is no longer potential ecological exposure from indoor products containing allethrins, and no further mitigation is necessary for indoor uses. Although current label uses include several potentially large-scale outdoor uses, they are not being supported by the technical registrant. Since outdoor uses will be limited to localized spot treatments, no additional mitigation measures for these uses are required.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or "the Agency"). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential risks arising from the currently registered uses of the pesticide, to determine the need for additional data on health and environmental effects, and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This document summarizes EPA's human health and ecological risk assessments and reregistration eligibility decision (RED) for the allethrins. The document consists of six sections. Section I contains the regulatory framework for reregistration; Section II provides an overview of the chemical and a profile of its use and usage; Section III gives an overview of the human health and environmental effects risk assessments; Section IV presents the Agency's decision on reregistration eligibility and risk management; and Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Finally, the Appendices list related information, supporting documents, and studies evaluated for the reregistration decision. The risk assessments for the allethrins and all other supporting documents are available in the Office of Pesticide Programs (OPP) public docket (http://www.regulations.gov) under docket number EPA-HQ-OPP-2006-0986.

II. Chemical Overview

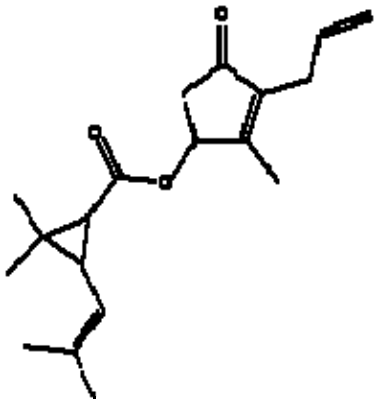
A. Regulatory History

The allethrin series of pyrethroid insecticides includes bioallethrin (PC code 004003), esbiol (004004), esbiothrin (004007, formerly 004003/004004), and pynamin forte (004005). Historically, there were two other members of the series, which have since been cancelled. Allethrin (allyl homolog of cinerin I), in its liquid form was assigned PC code 004001, and was cancelled in 1992. Allethrin in its solid form was assigned PC code 004002, and was cancelled in 1991. For a number of years, products containing esbiothrin were assigned a dual PC code (004003/004004), which led to some confusion in naming the active ingredients in registered pesticide products. To resolve this issue, in 2006, EPA established a separate PC code for products containing esbiothrin (004007). Due to the long history of the allethrins and the similarity between the allethrin compounds, there has been some additional confusion surrounding the allethrins nomenclature. During the reregistration process for the allethrins, the EPA has been in coordination with the two allethrins registrants, Valent BioSciences Corporation and Sumitomo Chemical Company, to help resolve some of these issues. To clarify, the revised chemical names, common names, and CAS numbers for the allethrins are listed in the next section, Chemical Identification.

EPA published a Registration Standard for the allethrins series in 1988, *Guidance for the Reregistration of Pesticide Products Containing Allethrin Stereoisomers as the Active Ingredient* (EPA 540/RS-88/063, issued March 24, 1988). The purpose of the Registration Standard was to "provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)." It also identified studies that were acceptable to meet the data requirements of the currently registered uses, additional studies necessary to support continued registration, and labeling revisions. It further identified steps registrants were required to take to maintain their registration or apply for new registrations. A data call-in (DCI) was issued as part of the Registration Standard, followed by a second DCI, which was issued on October 6, 1995.

B. Chemical Identification

ALLETHRINS:



The allethrins are synthetic pyrethroids, and are structurally very similar to cinerin I in naturally occurring pyrethrum. When allethrin was first synthesized in 1948, it was the first pyrethroid developed, and it differs from more recently developed pyrethroids in its photo-lability. The more-recently developed pyrethroids have structural modifications (*i.e.*, alterations to the isobutenyl group attached to the cyclopropane moiety) that make them more persistent than the early generation pyrethroids, such as allethrin. Therefore, allethrin is among the least persistent of all pyrethroids and is less persistent than allethrins, cyallethrins, cyfluthrin, cyhalothrin, deltamethrin, fenvalerate, tefluthrin, and tralomethrin. The allethrins subject to reregistration differ only in the percentage of stereoisomers present. There are three asymmetric carbons and, thus, eight potential isomers; however, four isomers are present in the greatest concentration for these products. One of the stereoisomers, d trans of d component (isomer), is recognized as being the most insecticidally active and toxicologically significant of the four isomers . Allethrins are sometimes classified as type I pyrethroids, since they lack an α-cyano substituent.

Chemical Class:	Sythetic pyrethroid
Case Number:	0437
PC Code:	Bioallethrin (004003), esbiol (004004), esbiothrin (004007), and pynamin forte (004005)
Molecular Weight:	302.4
Empirical Formula:	$C_{19}H_{26}O_3$
Technical Registrants:	Valent BioSciences Corporation (bioallethrin, esbiol, esbiothrin), Sumitomo Chemical Company, Ltd. (pynamin forte)

See below for a listing of common names, chemical names, PC codes, and CAS numbers.

Bioallethrin:

OPP Chemical Code: 004003

Chemical Name: (RS)-3-allyl-2-methyl-4-oxocyclopent-2-enyl (1R,3R)-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate

Common name: "bioallethrin (BSI)"

CAS number: 260359-57-7

Composition: consists of [1R,trans;1R] + [1R,trans;1S] in an approximate ratio of 1:1

Esbiol: (also called S-Bioallethrin for some products)

OPP Chemical Code: 004004

Chemical name: (S)-3-allyl-2-methyl-4-oxocyclopent-2-enyl (1R,3R)-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate

Common name: "allethrin (ISO)". ("Esbiol" is not an authorized common name.)

CAS number: 28434-00-6

Composition: consists predominately [> 96%] of the (S)(1R,3R) enantiomer.

Esbiothrin:

OPP Chemical Code: 004007

Chemical name: (RS)-3-allyl-2-methyl-4-oxocyclopent-2-enyl (1R,3R)-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate

Common name: "allethrin (ISO)". ("Esbiothrin" is not an authorized common name.)

CAS number: 260359-57-7

Composition: consists of [1R,trans;R] + [1R,trans;S] in approximate ratio of 1:3.

Pynamin Forte:

OPP Chemical Code: 004005

Chemical Name: (RS)-3-allyl-2-methyl-4-oxocyclopent-2-enyl (1R,3R; 1R,3S)-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate

Common name: "allethrin (ISO)". ("d-allethrin" is the chemical listed in the title of the WHO Specifications and Evaluations document, but is not recognized as an authorized common name; "d-cis/trans allethrin" is listed in information from the registrants as an even more appropriate name, but they state it also is not an authorized common name.)

CAS number: 231937-89-6

Composition: consists of [1R,trans;1R] + [1R,trans;1S] + [1R,cis;1R] + [1R,cis;1S] in an approximate ratio of 4:4:1:1

Two of the technical compounds have the same CAS Number; both esbiothrin and bioallethrin are 260359-57-7, since they are primarily comprised of the same two enantiomers. However, it would be preferable to have separate CAS Nos. assigned for these two technical products. In addition, note that the common names listed above are not distinctive, since there are three technical products currently known as "allethrin (ISO)". To resolve this, Valent Biosciences Corporation has informed the Agency that there are efforts on-going to assign distinctive common names for the respective technical products.

The analytical method used to verify the chemical identify of the members of the allethrin series can only distinguish the presence of trans and cis isomers. However, current analytical methods cannot determine their relative proportions in a sample. Since the different members of the allethrin series differ primarily in their relative proportions of the cis and trans isomers, the current Enforcement Analytical Method does not adequately distinguish the different members of the allethrin series. To address this area of uncertainty, the two technical registrants have agreed to submit analytical methods which will distinguish between the four allethrin technical products.

C. Use Profile

The following information on the currently registered uses includes an overview of use sites and application methods. A detailed table of the uses of allethrins eligible for reregistration is contained in Appendix A.

Type of Pesticide: Synthetic pyrethroid. The allethrins are insecticides, and are typically used as a "knock-down" agent. A different, residual pesticide is co-formulated with the allethrin in the end-use products to kill the target pests.

Target Organism: The primary target pests are wasps and hornets, roaches, ants, fleas, and mosquitos.

Mode of Action: The allethrins are a type I pyrethroid (i.e., lacking a cyano group at the α carbon position of the alcohol moiety). The allethrins are axonic poisons that block the closing of the sodium gates in the nerves, and, thus, prolong the return of the membrane potential to its resting state leading to hyperactivity of the nervous system which can result in paralysis and/or death.

Use Sites: Commercial applications include space, broadcast and crack and crevice treatments in a variety of commercial, industrial, residential, and institutional sites. Horticultural applications include foliar and fogger treatment on non-food plants. Residential uses include pest control in homes and outdoor domestic structures, on gardens, and direct application to pets.

There are no food uses for the allethrins, and a Federal Register final rule revoking all tolerances was published on September 29, 2004.

Use Classification: The allethrins products are designated as general use; however, some products are registered for use by pest control operators (PCOs) only.

Formulation Types: Pressurized liquid, ready-to-use (RTU) liquids, emulsifiable concentrates, liquid concentrates, pet shampoos and dips, mosquito coils and mats.

Application Methods: Allethrins are applied by power, mechanical, and commercial sprayer; aerosol can; and thermal fogger.

Application Rates: Typical concentrations of active ingredients (ai) in residential use products, including ready to use (RTU) (e.g. ant and roach sprays, wasp and hornet sprays) and indoor and outdoor aerosols or aqueous sprays for crawling and flying insects, range between 0.05 % and 0.25%. Total release aerosol (TRA) foggers are typically 0.6% to 3% (total volume of the can versus the area it is designed to treat). Mats range between 7% and 24% and release active ingredient into the air by heating the mat. Coils range from 0.1% to 0.3% in concentration and also release active ingredient into the air by burning of the coil (the active is volatilized off of the coil just behind the burning part of the coil.).

Application Timing: The application timing is generally not mentioned on existing allethrins labels, although some indicate re-application permitted after two weeks, while others recommend use as needed.

D. Estimated Usage of Pesticide

Less than 30,000 lbs of allethrins are marketed on average per year. Of the four allethrins, bioallethrin is the predominant form of allethrin sold in the U.S. Pynamin forte is used exclusively in the mat and coil formulations. The majority of allethrins are used in the consumer market (i.e. homeowner uses in space and surface sprays for flying and crawling insects), and a small amount is sold into the institutional/industrial market.

III. Summary of Allethrins Risk Assessments

The following is a summary of EPA's revised human health and ecological risk assessments for the allethrins, as presented fully in the documents, revised *Allethrins: Revised HED Chapter of the Reregistration Eligibility Decision Document (RED) for Bioallethrin (004003), Esbiol (004004), Esbiothrin (004007), and Pynamin Forte (004005) and Section 3 Registration Action for Use in Food Handling Establishments: Esbiothrin and Esbiol,* dated June 27, 2007, the *Response to Comments (Phase 3) and Revised Environmental Fate and Ecological Risk Assessment in Support of the Reregistration of the Allethrins,* dated April 4, 2007. The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the assessments.

The human health and ecological risk assessment documents and supporting information listed in Appendix C were used to reach the safety finding and regulatory decision for the allethrins. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket, located at http://www.regulations.gov, under docket number EPA-HQ-OPP-2006-0986.

EPA's use of human studies in the allethrins risk assessment is in accordance with the Agency's Final Rule promulgated on January 26, 2006, related to Protections for Subjects in Human Research, which is codified in 40 CFR Part 26.

A. Human Health Risk Assessment

The human health risk assessment incorporates potential exposure, hazard, and risks from all sources, which for the allethrins is limited. There are no registered food uses for the allethrins. The majority of allethrins use is in consumer home products (indoor and outdoor surface and space sprays). There are also commercial and horticultural uses for the allethrins. Although the allethrins human health risk assessment considered a pending new use for the allethrins in food handling establishments, this use, and the risks associated with it, are not subject to reregistration at this time. The pending use in food handling establishements will not be included in the reregistration eligibility decision for the allethrins. The Agency will address this action separately. For more information on the human health risk assessment, see *Allethrins: Revised HED Chapter of the Reregistration Eligibility Decision Document (RED) for Bioallethrin (004003), Esbiol (004004), Esbiothrin (004007), and Pynamin Forte (004005) and Section 3 Registration Action for Use in Food Handling Establishments: Esbiothrin and Esbiol,* dated June 27, 2007, which is available under docket number EPA-HQ-OPP-2006-0986.

1. Toxicity of Allethrins

Toxicity assessments are designed to predict whether a pesticide could cause adverse health effects in humans (including short-term or acute effects, such as skin or eye damage, and lifetime or chronic effects, such as cancer, developmental effects, or reproductive effects), and the level or dose at which such effects might occur. The Agency has reviewed all toxicity studies submitted for the allethrins and has determined that the toxicological database is reliable and sufficient for reregistration. However, there are no developmental neurotoxicity or comparative neurotoxicity

studies in adults and offspring available for the allethrins. Since the allethrins database is currently incomplete with respect to data on potential pre- and postnatal toxicity, the Agency applied a ten fold (10x) database uncertainty factor (UF_{DB}) to account for this lack of data. A study will be required to address uncertainty surrounding potential pre- and postnatal toxicity of the allethrins. The registrants should consult with the Agency before beginning this study.

a. Acute Toxicity Profile

Pyrethroids are neurotoxicants which act by prolonging the opening of the sodium channel in nervous tissue, resulting in a hyperexcitable state. As explained previously, the allethrins are classified as type I pyrethroids. Neurotoxicity in rats of type I pyrethroids is characterized as tremor, prostration, enhanced startle response, and aggressive behavior. Similar signs were observed in the guideline studies in which clinical signs of neurotoxicity were noted. The acute toxicity profile for each of the allethrins is summarized in Tables 1-4 below.

Table 1. Acute Toxicity Profile - Bioallethrins

Guideline	Study Type	MRID	Results	Toxicity Category[a]
870.1100	Acute Oral	00151444	LD_{50}: 709 mg/kg (M) 1042 mg/kg (F)	III
870.1200	Acute Dermal	41155801	LD_{50} > 3000 mg/kg (M&F)	III
870.1300	Acute Inhalation	42906902	LC_{50} : 2.51 mg/L	IV
870.2400	Primary Eye Irritation	41155803	Slight to moderate irritant	III
870.2500	Primary Skin Irritation	41155805	Very slight dermal irritant	IV
870.2600	Dermal Sensitization	41155807	Negative	N/A

a. These technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

Table 2. Acute Toxicity Profile - Esbiol

Guideline	Study Type	MRID	Results	Toxicity Category[a]
870.1100	Acute Oral	00151460	LD_{50}: 574.5 mg/kg (M) 412.9 mg/kg (F)	II
870.1200	Acute Dermal	41155802	LD_{50} > 2000 mg/kg	III
870.1300	Acute Inhalation	41670801	LC_{50} : 1.32 mg/L (M) 1.23 mg/L (F)	III
870.2400	Primary Eye Irritation	41155804	Moderate ocular irritant	III
870.2500	Primary Skin Irritation	41155806	Not a dermal irritant.	IV
870.2600	Dermal Sensitization	41155808	Not a sensitizer	N/A

a. These technical acute toxicity values included in this document are for informational purposes only.

The data supporting these values may or may not meet the current acceptance criteria.

Table 3. Acute Toxicity Profile - Esbiothrin				
Guideline	**Study Type**	**MRID**	**Results**	**Toxicity Category[a]**
870.1100	Acute Oral	00151449	LD_{50}: 432 mg/kg (M) 378.0 mg/kg (F)	II
870.1200	Acute Dermal	00151451	LD_{50} > 2000 mg/kg	III
870.1300	Acute Inhalation	00151452	LC_{50}: 2.63 g/m^3-unacceptable	III
870.2400	Primary Eye Irritation	00151454	Minimally	IV
870.2500	Primary Skin Irritation	00151453	Slightly	III
870.2600	Dermal Sensitization	42907001	Negative	N/A

a. These technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

Table 4. Acute Toxicity Profile – Pynamin Forte				
Guideline	**Study Type**	**MRID**	**Results**	**Toxicity Category[a]**
870.1100	Acute Oral	41017101	LD_{50}s= M: 2150 mg/kg F: 900 mg/kg	III
870.1200	Acute Dermal	41017102	M: 2660 mg/kg F: 4390 mg/kg	III
870.1300	Acute Inhalation	41017103	LC50 > 3.875 mg/L	IV
870.2400	Primary Eye Irritation	41017104	Slight irritant	III
870.2500	Primary Skin Irritation	41017104	Negative	IV
870.2600	Dermal Sensitization	41017105	Negative	N/A

a. These technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

b. Toxicological Endpoints

The toxicological endpoints used in the human health risk assessment for the allethrins are listed in Table 5 below. The observed endpoints for risk assessment were based on neurotoxicity and liver toxicity. Because observed endpoints for risk assessment were at the same or lower dose at which developmental and reproductive toxicity occurred, there were no concerns for sensitivity of offspring. Clinical signs of neurotoxicity occurred in an inhalation study with esbiol. The point of departure (POD) for intermediate-term incidental oral exposure was selected based upon a benchmark dose analysis because of the 6x difference between the NOAEL (6 mg/kg/day) and the LOAEL (36 mg/kg/day). A 10% response for the benchmark dose (BMD_{10}) was selected because of the mild nature of the lesions, characterized as "acute

swelling of hepatocytes," which did not progress in severity at the high dose. The selected $BMDL_{10}$ value was 267 ppm, which is the lower 95% confidence limit on the BMD_{10}. This dietary concentration was converted to a mg/kg/day dose. Only inhalation and incidental oral endpoints have been assessed, because no systemic effects were observed at the limit dose in the dermal toxicity studies in test animals, and no toxicity endpoint was selected for dermal exposure

The target MOE (i.e., level of concern) for residential incidental oral and inhalation exposures is 1000. This includes the standard uncertainty factors of 10X for interspecies extrapolation, 10X for intraspecies variation, and an additional 10X UF_{DB} due to lack of data on potential pre- and postnatal toxicity. The target MOE for occupational inhalation exposures is 100 because the database uncertainty factor does not apply to occupational exposures. The uncertainty factors (UF) used to account for interspecies extrapolation and intraspecies variability are also described in Table 5.

Table 5. Toxicology Endpoints for the Allethrins

Exposure/ Scenario	Point of Departure	Uncertainty Factors	RfD, PAD, Level of Concern	Study and Toxicological Effects
Incidental Oral Short-Term (1-30 days)	NOAEL = 20 mg/kg/day	UF_A = 10x UF_H = 10x UF_{DB} = 10x	Residential LOC for MOE = 1000.	30-day dog (esbiothrin). LOAEL = 63 mg/kg/day based on elevated liver enzymes and increased liver weight
Incidental Oral Intermediate-Term (1-6 months)	$BMDL_{10}$ = 8 mg/kg/day	UF_A = 10x UF_H = 10x UF_{DB} = 10x	Residential LOC for MOE = 1000.	6-month dog (Bioallethrin). $BMDL_{10}$ based on based on microscopic liver changes (hepatocellular degeneration)
Dermal (all durations)	N/A	N/A	N/A	No systemic toxicity at 1000 mg/kg/day with esbiothrin or esbiol and negligible dermal absorption with pyrethrins (0.22%)
Inhalation (all durations)	NOAEL = 1.3 mg/kg/day	UF_A = 10x UF_H = 10x UF_{DB} = 10x	Residential LOC for MOE = 1000. Occupational LOC for MOE = 100.	28-day inhalation study in rats (esbiol). LOAEL = 6.5 mg/kg/day based on clinical signs in females (limb tremors, hunched posture, vocalization during handling)
Cancer (oral, dermal, inhalation)	Classification: Suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential (esbiothrin).			

NOAEL = no observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (intraspecies). UF_H = potential variation in sensitivity among members of the human population (interspecies). UF_{DB} = database uncertainty factor. $BMDL_{10}$ = bench mark dose level. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

2. Carcinogenicity of Allethrins

Genetic toxicity studies with esbiol, esbiothrin, bioallethrin, and pynamin forte were negative for mutagenicity. Carcinogenicity studies were conducted with esbiothrin and pynamin forte. In these studies, the only evidence of carcinogenicity was rare benign kidney tumors in male rats treated with esbiothrin. Doses in the mouse carcinogenicity study were considered

inadequate and the cancer classification for esbiothrin is "suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential."

3. Metabolites and Degradates

The Agency reviewed the metabolism of allethrins, and concluded that for tolerance expression and risk assessment, the parent compound, allethrin, is the only residue of toxicological concern. For additional details, refer to *Allethrins: Revised HED Chapter of the Reregistration Eligibility Decision Document (RED) for Bioallethrin (004003), Esbiol (004004), Esbiothrin (004007), and Pynamin Forte (004005) and Section 3 Registration Action for Use in Food Handling Establishments: Esbiothrin and Esbiol,* dated December June 27, 2007.

4. Dietary Exposure and Risk (Food + Water)

There are no food uses for the allethrins currently registered; therefore, dietary exposure is not of concern. Although the human health risk assessment previously cited includes a dietary assessment for a proposed new use in food handling establishments, this action is not included in the allethrins reregistration case, and is outside the scope of this RED. The Agency will address this action separately. Because there are no outdoor, broadcast uses registered, the use of allethrins products is not expected to adversely impact groundwater or surface water (the sources of drinking water); therefore, a drinking water assessment was not performed.

5. Residential Exposure and Risk

Residential exposure assessments consider all potential non-occupational pesticide exposure. For allethrins, the Agency has evaluated potential exposure and risk to allethrins for homeowners who handle (mix, load, and apply) products containing allethrins. The Agency also evaluated potential post-application risk to adults and children entering allethrins-treated areas.

To estimate residential (inhalation and incidental oral) risks, the Agency calculates a margin of exposure (MOE), which is the ratio of the toxicity endpoint (NOAEL or $BMDL_{10}$) selected for risk assessment to the exposure. This MOE is compared to a level of concern, which is the same value as the uncertainty factor (UF) applied to a particular toxicity study. The standard UF is 100x (10x to account for interspecies extrapolation and 10x for intraspecies variation). Since the allethrins database is currently incomplete with respect to data on potential pre- and postnatal toxicity, the Agency applied a ten fold (10x) UF_{DB} to account for this lack of data. A study will be required to address uncertainty surrounding potential pre- and postnatal toxicity of the allethirns. Thus, the target level of concern for the allethrins is 1000. A summary of the allethrins residential risk follows. For further information on residential risk, refer to *Allethrins: Revised HED Chapter of the Reregistration Eligibility Decision Document (RED) for Bioallethrin (004003), Esbiol (004004), Esbiothrin (004007), and Pynamin Forte (004005) and Section 3 Registration Action for Use in Food Handling Establishments: Esbiothrin and Esbiol,* dated December June 27, 2007.

a. Residential Handler Risks

The Agency determined that there is the potential for residential handlers to be exposed to allethrins during pesticide applications from aerosol cans made in indoor and outdoor residential settings to several use sites. While some allethrin products are packaged as ready-to-use (RTU) trigger sprayer bottles, the handler risks calculated from aerosol can application are protective of risks from trigger sprayer applications because the unit exposure values are lower for trigger sprayer application. Only short-term (1-30 days) inhalation exposures were assessed because of the infrequency of use associated with the residential homeowner products. Dermal exposures were not assessed, because no dose or endpoints were selected from available toxicity studies for dermal exposure.

Pesticide handler exposure database (PHED) unit exposure values were used to assess exposures, because chemical-specific monitoring data were not available. The following assumptions were also used in estimating risks from residential handler exposure to allethrins:

- The body weight of an adult handler is 70 kg.
- One aerosol can is used per day. This assumption is based upon the HED Science Advisory Committee on Exposure SOP 12: "Recommended Revisions to the Standard Operating Procedures for Residential Exposure Assessment" (2/22/2001).
- An aerosol can contains 9 to 16 ounces by weight of product based upon currently registered labels.
- The percent ai in the products ranges from 0.10 to 0.50 percent by weight based upon currently registered labels.

Risk to homeowners handling allethrins products are below the Agency's LOC. The inhalation MOEs for all scenarios assessed are greater than 1000 (ranging from 15,000 to 70,000). See Table 6 for further detail.

Table 6. Residential Handler Risks for Aerosol Can Applications

Use Scenario	Percent Active Ingredient (AI) in Product	Amount of Product Used per Day	Amount of AI Used per Day	Inhalation MOE
Indoor Surface or Space Spray	0.50	One 15 ounce can	0.0047 lb	15,000
Pet and Bedding Spray	0.32	One 9 ounce can	0.0018 lb	39,000
Hand Held Yard and Patio Fogger	0.15	One 16 ounce can	0.0015 lb	46,000
Wasp and Hornet Nests	0.10	One 16 ounce can	0.0010 lb	70,000

b. Residential Post-Application Risks

The Agency uses the term "post-application" to describe exposures to individuals that occur as a result of being in an environment that has been previously treated with a pesticide. Unlike residential handler exposure, where the Agency assumed only adults will be handling and

applying allethrins products, individuals of varying ages can potentially be exposed when reentering or performing activities in areas that have been previously treated.

For the allethrins, inhalation exposures may occur when consumer-use space spray products, patio foggers, mosquito coils, or fly mats are used; therefore, inhalation exposures were assessed for adults and toddlers for these scenarios. Inhalation risk following application of space sprays by a professional applicator was not assessed, because treated areas are vacated prior to application and ventilated prior to re-occupancy; therefore, the Agency believes little or no post-application inhalation exposure will occur. Only short-term exposure was considered for inhalation risk, since the endpoint for inhalation exposures is the same for all durations of exposure.

Incidental oral exposures may occur after surface applications of the allethrins are made by a consumer or professional applicator to residential areas such as carpets, vinyl and flooring. Incidental oral exposures for these scenarios were, therefore, assessed for both adults and toddlers. Incidental oral exposure may also occur through contact with pets that have been treated with pet sprays or shampoos. Incidental oral exposures from pet spray applications were calculated; these MOEs are also protective of dip or shampoo applications, since the shampoos and dips are used at lower dilution rates than the spray formulations. Because there are different toxicological endpoints for short- and intermediate-term incidental oral exposures, MOEs for both durations were calculated.

Only inhalation and incidental oral exposures have been assessed; dermal exposures were not assessed, because no dose or endpoints were selected from available toxicity studies for dermal exposure. The following scenarios were assessed:

- Toddler incidental oral ingestion of residues on indoor surfaces after fogger treatment.
- Toddler incidental oral ingestion of residues on indoor surfaces after PCO broadcast surface treatment.
- Toddler incidental oral ingestion of residues on indoor surfaces after consumer spot surface treatment.
- Inhalation exposures from space spray application
- Inhalation exposures from mosquito coils and fly mats
- Inhalation exposures from yard and patio foggers
- Incidental oral exposures from pet sprays

Exposure data for assessing post-application exposures from the use of foggers and aerosols in indoor residential settings were based upon pyrethrin studies conducted by the Non-Dietary Exposure Task Force (NDETF). The pyrethrin study data are considered applicable for allethrin because of the structural similarity between pyrethrin and allethrin. The residential risk assessment is also based on current label rates and use instructions, as well as on estimates of what and how much homeowners typically treat, such as the size of a house or spot treatment, from the Agency's standard operating procedures for residential exposures and best professional judgment. For more information on the daily volume handled and the area treated used in each residential handler scenario, refer to both the *Allethrins: HED Chapter of the Reregistration Eligibility Decision Document (RED). Phase 2 Error Correction Reregistration Action for*

Bioallethrin (004003), Esbiol (004004), Esbiothrin (004007), and Pynamin Forte (004005) and Section 3 Registration Action for Use in Food Handling Establishments: Esbiothrin and Esbiol, dated December 20, 2006, and *Allethrins: Revised HED Chapter of the Reregistration Eligibility Decision Document (RED) for Bioallethrin (004003), Esbiol (004004), Esbiothrin (004007), and Pynamin Forte (004005) and Section 3 Registration Action for Use in Food Handling Establishments: Esbiothrin and Esbiol,* dated June 27, 2007 risk assessments, which are available under docket number EPA-HQ-OPP-2006-0986.

While the majority of the scenarios assessed are not of concern, there are several scenarios with MOEs below 1000 (i.e, exceeding the Agency's LOC). All of the residential post-application MOEs for the allethrins are summarized in Table 7 below, and the use scenarios exceeding the level of concern are in bold type. Mitigation measures addressing risk exceedances are discussed in Chapter IV of this document.

Table 7. Allethrin Residential Post-Application Risk Summary

Source of Exposure	Application Rate	Exposed Population	MOE*
Incidental Oral Exposures (Short-Term)			
Fogger Treatment - Carpet Floors Fogger Treatment - Vinyl Floors	3.6 mg/m^3	Children	3600 5200
PCO Surface Treatment - Carpet Floors PCO Surface Treatment - Vinyl Floors	3.0% spray (1 gal / 1000 ft^2)	Children	**20** **28**
PCO Surface Treatment - Carpet Floors PCO Surface Treatment - Vinyl Floors	0.1% spray (0.5 gal / 1000 ft^2)	Children	1200 1700
Consumer Spot Treatment - Carpet Floors Consumer Spot Treatment - Vinyl Floors	0.5% Spray	Children	1100 1700
Consumer Spot Treatment - Carpet Floors Consumer Spot Treatment - Vinyl Floors	0.25% Spray	Children	2200 3400
Treated Pets – Spray Formulations	0.32% a.i.	Children	2,100
Incidental Oral Exposures (Intermediate-Term)			
Fogger Treatment - Carpet Floors Fogger Treatment - Vinyl Floors	3.6 mg/m^3	Children	3000 4400
PCO Surface Treatment - Carpet Floors PCO Surface Treatment - Vinyl Floors	3.0% spray (1 gal / 1000 ft^2)	Children	**16** **24**
PCO Surface Treatment - Carpet Floors PCO Surface Treatment - Vinyl Floors	0.1% spray (0.5 gal /1000 ft^2)	Children	960 1400
Consumer Spot Treatment - Carpet Floors Consumer Spot Treatment - Vinyl Floors	0.5% Spray	Children	960 1400
Consumer Spot Treatment - Carpet Floors Consumer Spot Treatment - Vinyl Floors	0.25% Spray	Children	1900 2800
Treated Pets – Spray Formulations	0.32% a.i.	Children	**860**
Inhalation Exposures (Short/Intermediate-Term)			
Space Spray – 0.50% Product	0.80 mg/m^3 (based upon the NDETF study)	Children Adults	**650** 2100
Space Spray – 0.25% Product	0.40 mg/m^3 (based upon the NDETF study)	Children Adults	1300 4200

Table 7. Allethrin Residential Post-Application Risk Summary			
Source of Exposure	**Application Rate**	**Exposed Population**	**MOE***
Space Spray – 0.10% Product	0.16 mg/m^3 (based upon the NDETF study)	Children Adults	3050 10000
	0.35 mg/m^3 (Based upon Raid label 4822-513)	Children Adults	1400 4800
Mosquito Coils	2 coils per patio	Children Adults	7000 14000
Fly Mats	2 mats per patio	Children Adults	1800 3600
Hand Held Yard and Patio Fogger	3 second spray per patio	Children Adults	3100 6200
Hand Held Yard and Patio Fogger	9 second spray per patio	Children Adults	1000 2200
Total Release Yard and Patio Fogger	6 oz. fogger / yard & patio	Children Adults	**160** 310
Total Release Yard and Patio Fogger	Two 1.5 ounce foggers / patio	Children Adults	**650** 1300

*MOEs in bold font do not approach or exceed the target MOE of 1000 (i.e., indicate risks of concern).

6. Occupational Exposure and Risk

The occupational risk assessment addresses risks to workers who may be exposed to allethrins when mixing, loading, or applying a pesticide (i.e., handlers), and when entering treated sites for routine tasks (post-application). Exposure for workers generally occurs via the dermal or inhalation route; however, only inhalation exposures have been assessed because no systemic effects were observed at the limit dose in the dermal toxicity studies in test animals, and no toxicity endpoint was selected for dermal exposure. The Agency assessed short (1 to 30 days), intermediate (30 days to several months) and long-term (> 6 months) exposure, although the risk results were essentially the same since the toxicological endpoints for inhalation exposures are the same for all durations of exposure. The target MOE is 100 for short, intermediate and long-term inhalation exposures.

Occupational exposure to allethrins was assessed using data from the Pesticide Handler Exposure Database (PHED), and worker exposure and risk estimates are based on the best data currently available to the Agency. In addition, standard default assumptions pertaining to average body weight, work day, and area treated daily were used to calculate risk estimates. Application rates used in this assessment are derived directly from current allethrin labels. The occupational risk assessment is summarized here. For further detail, see the *Allethrins: Revised HED Chapter of the Reregistration Eligibility Decision Document (RED) for Bioallethrin (004003), Esbiol (004004), Esbiothrin (004007), and Pynamin Forte (004005) and Section 3 Registration Action for Use in Food Handling Establishments: Esbiothrin and Esbiol,* dated June 27, 2007.

a. Handler Exposure Risks

Occupational handler exposure assessments are conducted by the Agency using different levels of protection. The Agency typically evaluates all exposures with minimal protection and then adds protective measures in a tiered approach to determine the level of protection necessary to obtain appropriate MOEs. Since only inhalation exposures are of concern, only PPE relevant to the inhalation exposures were considered. The types of protection which were used to calculate inhalation occupational exposure from allethrins are as follows:

- Baseline: No respirator
- PF5 Respirator Filtering facepiece respirator (i.e., dust mask) with a protection factor of 5
- PF50 Respirator Full face respirator, with a protection factor of 50

Because most allethrin products are packaged in aerosol cans, the majority of the allethrin uses involve potential application exposures only; there are no mixing and loading exposures. There are also a few products packaged as ready-to-use (RTU) liquids or liquid concentrates, which are applied with mechanical sprayers, compressed air sprayers or foggers. These products are used in non-food commercial/ industrial/institutional areas, non-food greenhouses and non-food animal premises. Based upon these labels, the Agency assessed the following occupational handler scenarios:

Pesticide Control Operator Scenarios

1) Mix/Load/Apply (M/L/A) liquids with backpack sprayer or low-pressure (LP) handwand
2) Mix/Load/Apply liquids with high-pressure (HP) handwand
3) Mix/Load/Apply liquids with a fogger
4) Apply with aerosol can.

Risk estimates (i.e., MOEs) for the surface spray handler scenarios are summarized in Table 8. Most of the inhalation MOEs are above the target MOE of 100 without respirators (i.e., No Resp.) and, therefore, the inhalation risks are not of concern. The HP handwand scenario is of concern without respirators and requires a PF5 filtering facepiece respirator (i.e., dust mask) to achieve the target MOE.

Table 8. Occupational Handler Risks from Surface Spray Applications

Exposure Scenario	Dilution	Spray Dilution (Percent ai)	Amount Sprayed per Day	lb ai handled per day	Inhalation MOE
M/L/A liquids with LP hand-wand or backpack sprayer	Undiluted	3	40 gallons	10	300 – No Resp.
M/L/A liquids with LP hand-wand or backpack sprayer	Diluted in water	0.11	40 gallons	0.37	8100 – No Resp.
M/L/A liquids with HP hand-wand (Greenhouse Use)	Diluted in water	0.11	1000 gallons	9.2	**81 – No Resp.** 400 – PF5 Resp.

Table 8. Occupational Handler Risks from Surface Spray Applications					
Exposure Scenario	**Dilution**	**Spray Dilution (Percent ai)**	**Amount Sprayed per Day**	**lb ai handled per day**	**Inhalation MOE**
Aerosol Can application	Undiluted	0.54	6 (16 oz) cans	0.032	2300 – No Resp.

The risks for the space spray applications are summarized in Table 9. The MOEs are of concern (MOE < 100) when at all of the spray dilutions when respirators are not worn. At the highest spray dilution rate (3.0%), the MOEs are still of concern with a PF50 Full Face Respirators.

Table 9. Occupational Handler Risks from Space Spray Applications					
Label #	**Spray Dilution**	**Application Rate (lb ai/1000 ft^3)**	**Average Concentration (mg/m^3)**	**Respirator Worn**	**Inhalation MOE**
432-870	3.0	0.0020	16	None	**1.4**
1021-1478	1.5	0.0010	8.0		**2.8**
1021-1453	1.0	0.00067	5.4		**4.2**
432-870	3.0	0.0020	16	PF50 Full Face	**70**
1021-1478	1.5	0.0010	8.0		140
1021-1453	1.0	0.00067	5.4		210

b. Post-Application Exposure and Risk

The Agency uses the term "post-application" to describe exposures to individuals that occur as a result of being in an environment that has been previously treated with a pesticide (also referred to as reentry exposure). Allethrins are used as space sprays in a wide variety of indoor areas such as greenhouses, commercial institutions, and residences. For most of the commercial applicator labels, there are restrictions such as "Do not apply when people are present" or "Do not allow unprotected persons to enter until treated area has been thoroughly ventilated," which minimize post-application exposures. Given the use characteristics, occupational post- application inhalation exposures are anticipated primarily from time metered device applications.

To assess occupational post-application risk, a scenario that involves the metered release into an industrial work area was evaluated. The resulting occupational post-application inhalation MOE is 850, which is greater than the target MOE of 100 and, therefore, is not of concern. Furthermore, this risk estimate is conservative, because it was assumed that the aerosols would remain airborne until they were removed by ventilation and the effects of aerosol settling were not considered.

B. Environmental Risk Assessment

The outdoor uses for the allethrins are predominantly limited to foggers and spot treatments that are typically packaged as small, hand-held spray units and mosquito repellents

(mats and coils). Although current label uses include several large-scale outdoor uses, they are not being supported. Since the registrant agreed to modify labels to remove, or limit to spot treatment only, any outdoor uses that could potentially be used as a broadcast treatment, risk from broadcast uses were not assessed. Since the allethrins are currently registered for use in some pet products (pet shampoos and dips), there is potential for aquatic organism exposure from indoor use of the allethrins, via surface water exposure following the release of household wastewater. Therefore, the Agency assessed ecological risk from both indoor and outdoor uses of allethrins. Because most of the standard methods used by the Agency for assessing environmental risk are established for large-scale uses such as applications to agricultural fields or public health uses, the potential risk to the environment from allethrin spot treatment use is assessed qualitatively by considering uses, application methods, environmental fate properties, and toxicity data, and some risk quotients (RQs) were calculated for illustrative purposes.

A summary of the Agency's environmental fate and effects risk assessment is presented below. For detailed discussion of all aspects of the environmental risk assessment, please see the *Response to Comments (Phase 3) and Revised Environmental Fate and Ecological Risk Assesment in Support of the Reregistration of the Allethrins, dated April 4, 2007,* which is available under docket number EPA-HQ-OPP-2006-0986.

Terrestrial Organisms (Birds and Mammals)

The potential for risk to non-listed terrestrial organisms is limited or eliminated by the application methods described on the product labels. For instance, the use of Rainbow Wasp and Ant Spray (EPA Reg. No.13283-13) is intended as a spot treatment on wasp or other stinging insect hives. The registrant described the typical use of the spray as a 3-second directed application at a hive, which would result in an application of about 0.156 g to an area of about 1000 cm^2. This rate is equivalent to an application of about 13.8 lb ai/acre.

If this application rate is used as input to the TeRrestrial Exposure (T-REX) model, the acute and acute endangered species RQs for birds and mammals would exceed levels of concern (LOC). However, the exposure scenario is too unrealistic to expect risk to birds and mammals. To reach that level of exposure, birds or mammals would essentially need to consume the treated hive to ingest the allethrins applied by a directed spray.

The fogger application for the allethrins also represents an exposure scenario that is unlikely to result in risk to non-listed birds and mammals. The risk assessment considered exposure from the Raid Yard Guard Outdoor Fogger Formula VII (Reg. No. 4822-394), a total release fogger which could affect flying insects in a 15-by-15 foot area, releasing 1.07 g of allethrins along with another insecticide. If all the mass of allethrins were deposited in that 225 square-foot area, the application would be equivalent to about 0.47 lb ai/acre, and the resulting RQs would exceed the endangered species levels of concern for birds and mammals. However, that level of exposure to non-target birds and mammals is very unlikely. First, non-target animals would have to derive all of their food from the 15-by-15 foot area in which a person just placed a fogger, whether that area is a backyard patio or a lawn. Presumably, the fogger will have been placed in such an area so that people can be present, which makes the likelihood of feeding less likely. In addition, the fogger application is designed to keep the applied insecticides in the air, so that allethrins can work as a knockdown agent while the other

insecticide takes effect. The applied material is unlikely to deposit solely within the 15-by-15 foot area, but would be dispersed over a wider area at a lower rate, dissipated by wind and degraded by photolysis.

No guideline data were submitted to evaluate the risk of allethrin exposure to non-target plants. However, the allethrins are not expected to induce phytotoxic effects because of their neural toxic mode of action, and available efficacy studies indicated no phytotoxic effects.

Although the Agency does not currently have standard LOCs for terrestrial invertebrates, risk to non-target invertebrates were considered. Based on an average fresh weight per honey bee of 128 milligrams, the LD_{50} of honey bees (3.9 µg/bee) can be multiplied by 7.8 to determine the ppm toxicity. Therefore, the contact LD_{50} of 3.4 µg/bee for allethrins can be converted to 26.5 ppm. Using the 'fruits/pods/seeds/large insects' category in T-REX as a surrogate for bees and an application rate of 13.8 lb a.i./acre results in an EEC for bees of 207 ppm using upper-bound Kenaga values. This equates to an RQ of 7.8. Since the Agency does not have standard LOCs for terrestrial invertebrates, for illustration purposes, the LOCs for other terrestrial animals was used (i.e., acute risk LOC = 0.5; acute endangered species LOC = 0.1). Using upper-bound Kenaga values, the application rate needed to reach the acute risk LOC for bees is 3.5 lb a.i./acre (1,842 cans), and the application rate needed to reach the endangered species LOC is 0.18 lb a.i./acre (95 cans of product).

Aquatic Organisms

There is potential for exposure to aquatic organisms from both the outdoor and indoor uses of the allethrins, so both uses were assessed. The standard models used by the Agency to estimate transport to surface water simulate application to agricultural fields, and cannot estimate surface water concentrations which might result from spot treatments or fogger use. Therefore, for illustrative purposes, the aquatic exposure that would result from spraying a can of Rainbow Wasp and Ant Spray (EPA Reg. No. 13283-13) directly into the standard pond used in OPP aquatic exposure model standard scenarios was determined. Based on a pond volume of 20 million liters and a total of 0.884 g of allethrin (a.i.), and assuming no degradation or sorption, the resulting concentration in the pond would be 0.0442 ppb. In order to achieve an exposure concentration equal to the toxic endpoints of concern for freshwater invertebrates (LC_{50} = 2.1 ppb) and freshwater fish (LC_{50} = 7.9 ppb), it would require the direct spraying of approximately 48 and 179 cans of product. To exceed the acute endangered species LOC of 0.05 for aquatic animals, it would require the simultaneous release into a standard farm pond of 2.4 cans (for freshwater invertebrates) and 9 cans (for freshwater fish). Thus, since actual use entails spraying a fraction of a can in a spot treatment on land, aquatic risk of concern to aquatic organisms from the outdoor uses of the allethrins is not anticipated.

Since the allethrins are currently registered for use in some pet products (pet shampoos and dips), there is potential for surface water exposure following the release of household wastewater. However, it would require atypically large quantities of pet products containing allethrins to reach an exposure concentration equal to the toxic endpoints of concern for freshwater animals. A "super size" bottle (21.6 fluid ounces) of Hartz Control Flea and Tick Conditioning Shampoo for Dogs (EPA Reg. No. 2596-124) contains 0.109% allethrin a.i.

Assuming a conservative specific gravity for shampoo of 1.2 g/ml, a 21.6 ounce bottle of shampoo contains 766.6 g of product, including 0.836 g a.i. Therefore, a bottle of this product contains less active ingredient than a can of the wasp and hornet spray used in the example above and correspondingly higher numbers of bottles of shampoo would have to be released into the pond to result in risk exceedances.

1. Adverse Ecological Incidents

A search of the EIIS (Environmental Incident Information System) database for ecological incidents (run on Dec. 2, 2005) identified a total of one ecological incident involving an allethrin (allethrin; PC Code: 004001). The allethrin involved in the incident is no longer registered (*i.e.*, all of its uses have been cancelled). The incident occurred on a fish farm in Ventura County, CA, in Dec. 2000, and it involved the death of 13,000 rainbow trout. The reported cause of the incident was an act of sabotage (*i.e.*, it was the result of intentional misuse). The certainty index was reported as "highly probable" and it was reported that, "(t)here seemed to be no doubt about the cause of the fish kill," although no tissue or water samples were reported. Because the number of documented kills in EIIS is believed to be a very small fraction of total mortality caused by pesticides for a variety of reasons, absence of reports does not necessarily provide evidence of an absence of incidents given the nature of the incident reporting.

2. Endangered Species Considerations

Table 10 provides a matrix that depicts the potential for direct and indirect effects to listed species resulting from the use of allethrins.

Table 10. Listed species risk associated with direct or indirect effects due to applications of allethrins

Listed Taxon	Direct Effects[1]	Indirect Effects[2]
Terrestrial and semi-aquatic plants – monocots	None[3]	Possible[2]
Terrestrial and semi-aquatic plants - dicots	None[3]	Possible
Insects	None	Possible
Birds	No acute/ Possible chronic[2]	Possible
Terrestrial phase amphibians	No acute/ Possible chronic[2]	Possible
Reptiles	No acute/ Possible chronic[2]	Possible
Mammals	None	Possible
Aquatic vascular plants	None[3]	Possible
Freshwater fish	No acute/ Possible chronic[2]	Possible
Aquatic phase amphibians	No acute/ Possible chronic[2]	Possible
Freshwater crustaceans	No acute/ Possible chronic[2]	Possible
Mollusks	No acute/ Possible chronic[2]	Possible

Table 10. Listed species risk associated with direct or indirect effects due to applications of allethrins		
Marine/estuarine fish	No acute/ Possible chronic[4]	Possible
Marine/estuarine crustaceans	No acute/ Possible chronic[4]	Possible

[1]Although, LOCs were not calculated, exposures are expected to be below all Agency acute LOCs for all outdoor uses.
[2] Because of a lack of chronic data for all taxa except mammals, the potential for chronic direct effects or indirect effects cannot be dismissed.
[3] No guideline data were submitted to evaluate the risk of allethrin exposure to non-target plants, however, the allethrins are not expected to induce phytotoxic effects because of their neural toxic mode of action.
[4] No acute or chronic data are available.

Acute risks to listed species are not expected due to low application rates and the types of uses being assessed. Although the potential for chronic risk to any listed animal cannot be dismissed at this time because of a lack of available data, the very limited nature of ecological exposure from use of allethrin-containing products indicates that chronic risk is highly unlikely. However, a Not Likely to Adversely Affect (NLAA) determination for potential chronic risk to listed species would require a more definitive assurance that adverse, chronic effects would not occur.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing the allethrins as active ingredients. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing the allethrins.

The Agency has completed its assessment of the human health and ecological risks associated with the use of pesticide products containing the allethrins. The Agency has determined that allethrin-containing products are eligible for reregistration provided that label amendments are made as outlined in Chapter V. Appendix A summarizes the uses of the allethrins that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of the allethrins, and lists the submitted studies that the Agency found acceptable.

Based on its evaluation of the allethrins, the Agency has determined that products containing allethrins, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from the use of the allethrins. If all changes outlined in this document are incorporated into the product labels, then all current risks for the allethrins will be adequately mitigated for the purposes of this determination under FIFRA.

B. Public Comment Period

Through the Agency's public participation process, EPA worked with stakeholders and the public to reach the regulatory decisions for the allethrins. EPA released the allethrins preliminary risk assessments for public comment on December 27, 2006, for a 60-day public comment period (Phase 3 of the public participation process). During the public comment period on the risk assessments, which closed on February 26, 2007, the Agency received comments from the technical registrants, the California Regional Water Quality Control Board, S.F. Bay Region, and the California Stormwater Quality Association (CASQA). These comments in their entirety, responses to the comments, as well as the preliminary and revised risk assessments, are available in the public docket (OPP-2006-0986) at http:www.regulations.gov.

C. Regulatory Position

1. Regulatory Rationale

The Agency has determined that products containing allethrins are eligible for reregistration provided that specified label amendments are made. The following is a summary

of the rationale for managing risks associated with the use of allethrins. Where labelling revisions are warranted, specific language is set forth in the summary table of Section V.

a. Human Health Risk Management

i. Occupational Risk Mitigation

The occupational handler exposure scenarios that were assessed included surface spray applications using a low-pressure handwand, high-pressure handwand or aerosol can, and indoor space spray applications using handheld foggers. All estimated MOEs for surface sprays are above the target MOE of 100 and the risks are not of concern, except for the high pressure handwand scenario. This scenario is of concern with an MOE of 81 and a PF5 filtering facepiece respirator (i.e., a dust mask) is required to achieve the target MOE. The handheld fogger scenario is also of concern with MOEs ranging from 1.4 (spray dilution rate of 3.0%) to 4.2 (spray dilution of 1.0%) with no respirator. To mitigate occupational handler risk from handheld fogger applications, the maximum spray dilution rate will be reduced from 3.0% to 1.5%, and a Full Face respirator will be required, resulting in an MOE of 140, which is below the Agency's LOC.

Occupational post-application inhalation exposures were assessed, and risks were below the Agency's level of concern (i.e., MOEs were above 100 for all scenarios assessed); therefore, no mitigation measures are required.

ii. Residential Risk Mitigation

Handler Risk

Residential handler exposures were assessed for aerosol can application to a variety of use sites. All of the handler MOEs exceed the target MOE of 1000; therefore, the handler risks are not of concern, and no mitigation measures are required.

Post-Application Risk (Inhalation Exposure)

Residential post-application inhalation exposures from consumer-use products were assessed for consumer-use space sprays, yard and patio foggers, mosquito coils and fly mats. The short/intermediate-term inhalation MOEs for consumer-use space sprays, when assessed at the highest labeled application rate of 0.50% ai, range from 650 to 2100 for children and adults, respectively. The registrant has agreed to reduce the application rate on surface sprays to 0.25%, and when calculated at this reduced rate, the MOEs range from 1300 to 4200 for children and adults, respectively. Since the lowest MOE (1300) is above the target level of concern of 1000, no additional mitigation is necessary.

The 6 oz. yard and patio fogger, with MOEs ranging from 160 to 310, will be voluntarily cancelled by the technical registrant. The 1.5 oz. yard and patio fogger scenario is only of concern when the product is in the form of a total release fogger. The yard and patio scenario is not of concern when the product is in the form of a hand-held fogger. Although both product

forms are on the same product label (registration number 4822-394), the hand-held form is more typically found on retail shelves and likely represents the majority of usage. This is supported by the Residential Exposure Joint Venture (REJV) survey which indicated that most of the allethrin-containing yard and patio fogger products in the household inventory were hand-held foggers. The hand-held fogger contains approximately 454 grams of product, which is enough for approximately 9 sprays based upon the nozzle discharge rate of 6 grams per second and a spray duration of 9 seconds. By contrast, the total release foggers can only be used once, because they discharge their entire contents upon activation. It should also be noted that the toxicological point of departure (POD) selected to assess inhalation exposures (see Table 5), which is a NOAEL of 1.3 mg/kg/day observed in the inhalation study, may be an artifact of dose spacing, because it is five times lower than the LOAEL of 6.5 mg/kg/day. For this scenario, the estimated MOE is 650 with a NOAEL of 1.3 mg/kg/day; however, with only a slightly higher NOAEL of 2.0 mg/kg/day, the estimated MOE would be 1000. Considering the dose spacing for this study, the Agency has minimal concern with an estimated MOE of 650 for this scenario; thus, no mitigation is necessary.

Post-Application Risk (Incidental Oral Exposure)

Residential post-application incidental oral exposures were assessed for consumer applied indoor foggers, PCO-applied broadcast surface sprays, and consumer-applied spot treatment surface sprays. The MOEs for most consumer-use scenarios are greater than 1000, and are not of concern. The estimation of residue levels, and associated incidental oral risk, that result from consumer surface applications using aerosol can products for the allethrins were variable, depending upon the products' directions for use and the percent a.i. in the product. Although the application rates range from 0.5% to 0.05%, most of the variability in estimated exposures was based on the use directions for the products. Some consumer-use surface sprays containing allethrins specify that only spot treatments be made to areas such as cracks and crevices in walls, corners of rooms, cabinets, closets, along and behind baseboards, beneath and behind sinks, stoves, refrigerators and cabinets, around plumbing and other utility installations and wherever else these pests may find entrance. Several labels also include instructions to treat carpets by covering the entire surface until slightly moist. A broadcast use of a surface spray containing allethrins is not typical, and these uses were not assessed, because the registrant voluntarily agreed to amend labels to restrict use to spot treatment only. The incidental oral MOEs from consumer surface spray products, when limited to spot treatments only, are greater than or approaching the target MOE of 1000 and not of concern. The technical registrant also agreed to reduce the application rate to 0.25% for consumer use surface sprays. With this mitigation, the MOEs for children with spot treatments applied to carpet are 1900, and therefore, no additional mitigation is necessary.

Residential post-application incidental oral risk estimates from PCO uses are less than the target MOE at the highest currently registered concentration of 3% a.i, with MOEs ranging from 16 (intermediate-term exposure on carpet) to 28 (short-term exposure on vinyl). To mitigate this risk, the registrant has agreed to limit the residential PCO product labels to a 0.1% a.i. spray dilution rate, and amend labels to reduce the volume of product to be applied from 1 gallon per 1000 sq ft to 0.5 gallons per 1000 square feet. This will result in intermediate-term incidental oral MOEs for children greater than or approaching the target MOE of 1000, and are not of concern.

Risk to children playing with pets that have been treated with pet sprays containing allethrins was also assessed. The short- and intermediate-term incidental oral MOEs were 2100 and 860, respectively. To mitigate risk from the pet sprays and other pet uses, the registrants have agreed to cancel all pet uses. Therefore, risk from pet sprays containing allethrins is no longer of concern.

The following is a summary of the human health mitigation measures:

- The residential PCO product labels will be limited to a 0.1% spray dilution rate, and language to labeling will be added reducing the volume from 1 gallon per 1000 sq ft to 0.5 gallons per 1000 square feet.

- The maximum spray dilution for indoor fogging applications will be reduced from 3.0 percent (as listed on the Esbiol 300 Insect label, Reg. No. 432-870) to 1.5 percent.

- For occupational handlers applying surface sprays with high pressure handwands, a PF5 filtering facepiece respirator (i.e. a dust mask) will be required in order to reach the target MOE of 100.

- For occupational handlers applying space sprays with handheld foggers, a PF50 Full Face respirator with appropriate cartridges will be required in order to reach the target MOE of 100.

- The consumer surface spray product labels will be changed to require spot treatment only. The broadcast surface applications to rugs and carpets will be eliminated.

- The consumer surface and space sprays, with concentrations currently ranging from 0.5% to 0.05% ai in products, will be limited to 0.25% ai.

- The use of the 6 ounce outdoor total release fogger will be deleted from the Raid Yard Guard label (4822-394).

- The pet uses (aerosol sprays and shampoos) will be cancelled.

b. Ecological Risk Management

The Agency evaluated potential ecological risk from both indoor and outdoor uses of the allethrins. The technical registrant voluntarily agreed to cancel pet shampoos and dips; therefore, there is no longer potential ecological exposure from indoor products containing allethrins, and no further mitigation is necessary for indoor uses.

Although current label uses include several potentially large-scale outdoor uses, they are not being supported by the technical registrant. Thus, the registrants have agreed to make the following changes to the allethrins labels:

- Uses on boat/ship hulls will be deleted.

- Kennels/stables and commercial premise uses (outdoor and area sprays) will be deleted or limited to spot treatments.

- Outdoor ornamental use sites will be specified and will be limited to spot use.

- Outdoor mosquito adulticide use will be deleted or limited to localized spray.

- Outdoor commercial area space spray uses will be limited to localized treatments.

- Perimeter spray uses will be limited to localized treatments.

- Uses in or on drainage systems, golf course turf, wide area/general outdoor treatment, airports/landing fields, uncultivated agricultural areas, and paved areas such as sidewalks and roads will all be deleted.

Because outdoor uses will be limited to localized spot treatments, no additional mitigation measures for these uses are required.

2. Endocrine Disruptor Effects

Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, individual pesticides may be subject to additional screening and/or testing. However, in the available toxicity studies for the allethrins, there was no evidence of endocrine disruption.

3. Endangered Species

The Endangered Species Act required federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on federally listed endangered and threatened species, and to implement mitigation measures that address these impacts. To assess the potential of registered pesticide uses that may affect any particular species, EPA puts basic toxicity and exposure data developed for the REDs into context for individual listed species and considers ecological parameters,

pesticide use information, the geographic relationship between specific pesticide uses and species locations and biological requirements and behavioral aspects of the particular species. When conducted, these analyses take into consideration any regulatory changes recommended in this RED being implemented at that time. A determination that there is a likelihood of potential effects to a listed species may result in limitations on the use of the pesticide, other measures to mitigate any potential effects, and/or consultations with the Fish and Wildlife Service or National Marine Fisheries Service, as necessary. If the Agency determines use of allethrins "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402).

The ecological assessment that EPA conducted for this RED does not, in itself, constitute a determination as to whether specific species or critical habitat may be harmed by the pesticide. Rather, this assessment serves as a screen to determine the need for any species specific assessment that will evaluate whether exposure may be at levels that could cause harm to specific listed species and their critical habitat. That assessment refines the screening-level assessment to take into account the geographic area of pesticide use in relation to the listed species, the habits and habitat requirements of the listed species, etc. If the Agency's specific assessments for allethrins result in the need to modify use of the pesticide, any geographically specific changes to the pesticide's registration will be implemented through the process described in the Agency's Federal Register Notice (54 FR 27984) regarding implementation of the Endangered Species Protection Program.

The Agency has reviewed data and other information for the allethrins and concludes that this series of insecticides does not pose a risk of direct acute effects to any species listed under the Endangered Species Act, because EPA's screening-level, qualitative assessment indicates that these uses are not likely to adversely affect listed species on an acute basis. The likelihood of adverse effects from chronic exposure to mammals is also considered low. However, the potential risk to all other taxa from chronic exposure to allethrins cannot be assessed at this time due to a lack of data.

D. Labeling Requirements

In order to be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing the allethrins. For the specific labeling statements, refer to Section V of this RED document.

V. What Registrants Need to Do

The Agency has determined that products containing allethrins are eligible for reregistration provided that the required label amendments are made. The Agency intends to issue Data Call-In Notices (DCIs) requiring product-specific data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. For product-specific data, the registrant will have eight months to submit data. Below are the label amendments that the Agency intends to require for the allethrins to be eligible for reregistration.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of the allethrins for currently registered uses has been reviewed and determined to be substantially complete. However, a few data gaps remain, and these are listed below.

Occupational Exposure
875.1400 Inhalation Exposure Indoor

Residue Chemistry
860.1650 Submittal of Analytical Reference Standards

Toxicology
Since the allethrins database is currently incomplete with respect to data on potential pre- and postnatal toxicity, the Agency is requiring a study to address this uncertainty. The Agency is currently evaluating whether a developmental toxicity study (DNT) or another comparative toxicity study would be best-suited for addressing the concerns for sensitivity to young animals. The registrants should consult with the Agency before beginning a study to fulfill this data requirement.

2. Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, manufacturing-use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the labeling contained in Tables 11 and 12.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data

meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI), outlining specific data requirements. For any questions regarding the PDCI, please contact Bonnie Adler at 703-308-8523.

2. Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Tables 11 and 12. Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. However, specific existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors.

C. Labeling Changes Summary Table

In order to be eligible for reregistration, amend all product labels to comply with the following table. Tables 11 and 12 describe how language on the labels should be amended.

Table 11. Summary of Labeling Changes for All Allethrin Uses EXCEPT for Use in Coils and Mats (See Table 12 for labeling requirements in coils and mats.)

Description	Amended Labeling Language	Placement on Label
Manufacturing Use Products		
For all Manufacturing Use Products	"Only for formulation into an ***insecticide*** for the following use(s) [fill blank only with those uses that are being supported by MP registrant]." "Not for formulation into end use products with directions for use as an application directly to pets." "Formulation into ready-to-use total release foggers with directions for use outdoors is limited to a maximum of 1.5 ounces of product per container." "Formulation into products with directions for use as a spot treatment is limited to a maximum 0.25% a.i. dilution strength." "Formulations with greater than 0.1% a.i. dilution strength must contain directions for use limiting applications in indoor residential settings to spot treatments only. Indoor broadcast use must be prohibited." "Formulation into products with directions for use as a broadcast spray outdoors is prohibited. Outdoor use is limited to spot treatments only." (NOTE: outdoor broadcast use with ready-to-use total release foggers is permitted.) "Not for formulation into products for use in or on drainage systems, golf course turf, airports/landing fields, uncultivated agricultural areas, boat/ship hulls, and paved areas such as sidewalks and roads."	Directions for use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of	Directions for Use

Table 11. Summary of Labeling Changes for All Allethrin Uses EXCEPT for Use in Coils and Mats (See Table 12 for labeling requirements in coils and mats.)		
Description	**Amended Labeling Language**	**Placement on Label**
additional uses supported by a formulator or user group	such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	
Environmental Hazards Statements	"ENVIRONMENTAL HAZARDS" "This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Eliminations System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency."	Precautionary Statements: Environmental Hazards
End-Use Products Intended for Occupational Use (WPS and Non-WPS)		
PPE Requirements[1] for Ready To Use (RTU) Formulations (RTU Liquids and Pressurized Liquids)	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are [registrant inserts correct material(s)]." For more options, follow the instructions for category [insert A, B, C, D, E, F, G or H] on the chemical-resistance category selection chart. "Applicators and other handlers must wear: long-sleeved shirt and long pants, and shoes and socks."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements for Liquid Concentrates including Emulsifiable Concentrates Note: If the use of high pressure handwands or handheld foggers in	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are [registrant inserts correct material(s)]." For more options, follow the instructions for category [insert A, B, C, D, E, F, G or H] on the chemical-resistance category selection chart.	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Table 11. Summary of Labeling Changes for All Allethrin Uses EXCEPT for Use in Coils and Mats (See Table 12 for labeling requirements in coils and mats.)		
Description	**Amended Labeling Language**	**Placement on Label**
enclosed areas is prohibited or is not feasible for the end-use product, the statement requiring respirators for those uses may be omitted.	"Applicators and other handlers must wear: long-sleeved shirt and long pants, and shoes and socks." "In addition to the above PPE, applicators using high-pressure handwands in an enclosed area must wear a NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or a NIOSH-approved respirator with any N*, R, P, or HE filter." "In addition to the above PPE, applicators using hand-held foggers in an enclosed area must wear a full-face, or helmet/hood-style NIOSH-approved respirator with: -- a dust/mist filtering cartridge (MSHA/NIOSH approval number prefix TC-21C), or -- a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or -- a cartridge or canister with any N*,R, P or HE filter." *Instruction to Registrant: Drop the "N" type prefilter from the respirator statement, if the pesticide product contains or is used with oil.	
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." "Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
User Safety Recommendations	"User Safety Recommendations" "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/ PPE immediately if pesticide gets inside, then wash thoroughly and put on clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals (Must be placed in a box.)

Table 11. Summary of Labeling Changes for All Allethrin Uses EXCEPT for Use in Coils and Mats (See Table 12 for labeling requirements in coils and mats.)		
Description	**Amended Labeling Language**	**Placement on Label**
	"Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	
Environmental Hazards Statements for Products Labeled for Outdoor Uses	"ENVIRONMENTAL HAZARDS" "This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present, or to inter-tidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwater or rinsate."	Precautionary Statements: Hazards to Humans and Domestic Animals
Environmental Hazards Statements for Products Labeled for Indoor Uses Only	"ENVIRONMENTAL HAZARDS" "This product is toxic to fish and aquatic invertebrates. Do not contaminate water when disposing of equipment, washwater, or rinsate. See Directions for Use for additional precautions and requirements." **For indoor commercial, industrial or institutional products packaged in containers equal to or greater than 5 gallons or 50 lbs add the following statement:** "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements: Hazards to Humans and Domestic Animals
Restricted-Entry Interval for Products with Directions for use Within Scope of the Worker Protection Standard for Agricultural Pesticides (WPS) *For Products Subject to WPS as required by Supplement 3 of PR Notice*	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours."	Directions for Use, Under Agricultural Use Requirements Box

Table 11. Summary of Labeling Changes for All Allethrin Uses EXCEPT for Use in Coils and Mats (See Table 12 for labeling requirements in coils and mats.)		
Description	**Amended Labeling Language**	**Placement on Label**
93-7		
Early Entry Personal Protective Equipment *For Products Subject to WPS as required by Supplement 3 of PR Notice 93-7*	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water, is coveralls, shoes and socks, and chemical-resistant gloves made of any waterproof material."	Directions for Use, in Agricultural Use Requirements Box
Entry Restrictions for Non WPS Uses	**Entry Restriction for product applied as a surface spray:** "Do not enter or allow unprotected persons to enter until treated areas have dried." **Entry Restriction for products applied as a space spray:** "Do not allow unprotected persons to enter until vapors, mists, and aerosols have dispersed, and the treated area has been thoroughly ventilated." **Entry Restriction for products formulated as total release aerosol foggers with directions for use indoors:** "Do not re-enter building for four hours, then open exterior doors and windows and allow to air for 60 minutes before reoccupying area."	If no WPS uses on the product label, place the appropriate statement in the Directions for Use Under General Precautions and Restrictions. If the product also contains WPS uses, then create a Non-Agricultural Use Requirements box as directed in PR Notice 93-7 and place the appropriate statement inside that box.
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	Place in the Directions for Use directly above the Agricultural Use Box
Application Restrictions- Indoor Surface Sprays in Residential Settings	Application rates for broadcast use indoors in residential settings are limited to no greater than 0.1% active ingredient dilution strength. **NOTE to Registrant**: the end-use product label must provide specific dilution instructions for attaining this maximum dilution strength. "When applied as a broadcast spray indoors in residential settings, use is limited to no more than 0.5 gallons dilute spray per 1000 square feet."	Place in the Directions Under Application Restrictions.

Table 11. Summary of Labeling Changes for All Allethrin Uses EXCEPT for Use in Coils and Mats (See Table 12 for labeling requirements in coils and mats.)		
Description	**Amended Labeling Language**	**Placement on Label**
Application Restrictions- Residential Handheld Fogger Use	Application rates for products labeled for indoor fogger use are limited to a maximum of 1.5% active ingredient dilution strength. **NOTE to Registrant**: the end-use product label must provide specific dilution instructions for attaining this maximum dilution strength.	Place in the Directions Under Application Restrictions.
Application Restrictions- Outdoor Uses, except on total release foggers for use outdoors.	"Outdoor uses are limited to spot treatments only. Broadcast applications are prohibited."	Place in the Directions Under Application Restrictions.
End Use Products Primarily Used by Consumers/Homeowners		
Environmental Hazards Statement	"ENVIRONMENTAL HAZARDS" "This product is toxic to fish and shrimp aquatic invertebrates. Do not apply directly to water. Do not contaminate water when cleaning equipment or disposing of equipment washwaters or rinsate." "Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas."	Precautionary Statements under Environmental Hazards
Entry Restrictions	Products applied as a spray: "Do not allow adults, children, or pets to enter the treated area until sprays have dried."	Directions for use under General Precautions and Restrictions
General Application Restrictions	"Do not apply this product in a way that will contact adults, children, or pets, either directly or through drift."	Place in the Direction for Use
Application Restrictions- for Indoor Use at Residential Sites	Surface and space sprays will be limited to concentrations no greater than 0.25% a.i. Surface spray uses are limited to spot treatments only. Broadcast surface applications are prohibited".	Application Restrictions- for Indoor Use at Residential Sites

[1] PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Table 12. Summary of Labeling Changes for Allethrins Used in Coils and Mats Only		
Description	**Amended Labeling Language**	**Placement on Label**
Manufacturing Use Products		
For all Manufacturing Use Products	"Only for formulation into an ***insecticide*** for the following use(s) [fill blank only with those uses that are being supported by MP registrant]."	Directions for use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements	"ENVIRONMENTAL HAZARDS" "This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Eliminations System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency."	Precautionary Statements: Environmental Hazards
End Use Products Primarily Used by Consumers/Homeowners		
Environmental Hazards Statement	"ENVIRONMENTAL HAZARDS" "This product is toxic to fish and shrimp. Do not apply directly to water. Do not contaminate water when cleaning equipment or disposing of equipment washwaters or rinsate." "Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas."	Precautionary Statements under Environmental Hazards